REMARKS

Claims 1-5, 9, 11-13, 15-21, 23-25, 27-29 and 31-33 are all the claims pending in the application.

I. Response to Rejection of Claims 1-4, 13, 15, 16, 18-20, 29, 31 and 32

Claims 1-4, 13, 15, 16, 18-20, 29, 31 and 32 are rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Yamada et al (publication, June 26, 2002; JP '562), as evidenced by PDRHealth.

Applicants respectfully traverse the rejection for the reasons of record and for the following reasons.

In the Office Action, the Examiner indicates that it is not clear what applicant means by "a free fatty acid" and that PDRHealth reference discloses that phosphatidycholine comprises the fatty acids of component (c). The Examiner also asserts that egg lecithin is used in the prior art in the same composition and amount, and since a chemical composition and its properties are inseparable, the prior art teaches egg lecithin as a stabilizer.

Applicants respectfully disagree.

JP '562 discloses a composition containing 0.5-2.0 w/v% of propofol, about 5-20 w/v% of vegetable oils, 0.5-5 w/v% of phospholipids, 0.05-0.5 w/v% of stabilizer, and 0.1-0.5 w/v% of lidocaine (Paragraph No. [0015]). The vegetable oils, phospholipids and lidocaine used in the composition of JP '562 correspond to the oil component, the emulsifier and the local anesthetic of claim 1. However, the stabilizers utilized in the examples and described (having HLB of 10 or more) in JP '562, i.e., polyoxyethylene (HCO-60) (HLB 14), (60) hydrogenated castor oil sodium lauryl sulfate (HLB 40), polysorbate (HLB 15), mono-coconut acid polyoxy

(HLB 17), ethylene sorbitan mono lauric acid deca glyceryl (HLB 15.5) and polyoxyethylene (HLB 16), do not meet the requirements of (a) to (d) recited in the present claims.

However, as noted above, the Examiner asserts that egg lecithin corresponds to the claimed stabilizer. If egg lecithin is considered as corresponding to the claimed stabilizer, then the fat emulsion preparation of Example 1 would be missing an emulsifier. In this regard, the Examiner appears to consider the soy bean oils as corresponding to both the claimed emulsifier and the claimed oily component. However, an emulsifier is used to emulsify oil components in water, and hence does not function as an emulsifier if it is identical to the oil component. Thus, an oily component, i.e., soy bean oils, would not function as an emulsifier.

Therefore, JP '562 does not anticipate claims 1, 18 and 33 since the composition of JP '562 is missing a claimed element ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.")

Further, the Examiner indicates that it is not clear what applicant means by "a free fatty acid" and that PDRhealth reference discloses that phosphatidycholine comprise the fatty acids of component (c). It is submitted that a free fatty acid is a fatty acid that is in its free form, i.e., not in the base or salt form.

In addition, even if the meaning of "a free fatty acid" is not clear, claims 1, 18 and 33 recite "at least one fatty acid selected from the group consisting of C_{10-12} linear or branched, saturated or unsaturated fatty acids." This phrase means that the fatty acid has a terminal carboxyl radical (COOH).

To the contrary, R and R_1 in a chemical formula of phosphatidylcholine shown in the PDRhealth reference are not fatty acids, but are recited as fatty acid residues, which bond to a main chain by ester linkages. Thus, phosphatidylcholine is clearly different from component (c) recited in claims 1, 18 and 33, in that the former is not a fatty acid that has a terminal carboxyl radical (COOH). Further, phosphatidylcholine is also different from components (a) and (b) recited in claims 1, 18 and 33. Therefore, egg lecithin does not qualify as a stabilizer within the scope of claims 1, 18 and 33, and JP '562 does not disclose the stabilizers used in the present invention at all.

For the above reasons, JP '562 does not anticipate the composition of claim 1, 18 and 33, and it is respectfully submitted that claims 1-4, 13, 15, 16, 18-20, 29, 31 and 32 are patentable over JP '562.

Accordingly, withdrawal of the rejection is respectfully requested.

II. Response to Rejection of Claims 5, 7-9, 11, 12, 21, 23-25, 27, 28 and 33 Under 35 U.S.C. § 103

Claims 5, 7-9, 11, 12, 21, 23-25, 27, 28 and 33 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over JP '562, as evidenced by PDRHealth, and further in view of Unger et al (USP 6,090,800).

Applicants respectfully traverse the rejection for the reasons of record and for the following reasons.

The egg yolk lecithin disclosed in JP '562 is not a stabilizer for the reasons discussed above. In particular, egg yolk lecithin is structurally different from the stabilizer of claims 1, 18 and 33. Thus, JP '562 does not disclose the composition of claims 1, 18 and 33. Accordingly, claims 5, 7-9, 11, 12, 21, 23-25, 27, 28 and 33, which depend directly or indirectly from claims

1, 18 or 33, are patentable for at least the same reasons as claims 1, 18 and 33.

In addition, with respect to the phospholipids having specific numbers of carbon atoms recited in claim 5, the Examiner asserts that Unger discloses distearoylphosphatidylglycerol, palmitic acid, stearic acid, oleic acid, dioleylphosphatidylethanolamine, distearoylphosphatidylethanol-amine-polyethylene glycol 5000, etc. as examples of stabilizers for pharmaceutical compositions.

Unger describes that the above components are useful as stabilizers, but does not provide any guidance or advantages in selecting those specific stabilizers among the numerous stabilizers exemplified in Unger. In addition, Unger does not disclose a specific fat emulsion containing propofol, an oily component, and an emulsifier, as a phamaceutical composition that can contain such stabilizers. Usefulness of an emulsifier must be determined in the relationship with other components, and a specific substance can not be said to be useful as an emulsifier for all pharmaceutical compositions without considering other components and the state of a composition. Therefore, it is submitted that there is no reasonable expectation that the stabilizers described in Unger would provide sufficient emulsion stability in a specific fat emulsion comprising propofol, an oily component, and an emulsifier, when a local anesthetic is admixed.

Furthermore, as mentioned above, JP '562 discloses a fat emulsion comprising an O/W-type emulsion containing propofol and lidocaine; it merely discloses a hydrophilic surfactant of 10 or more HLB as a stabilizer. Table 1 of JP '562 presenting the stability test results of some stabilizers does not include stabilizers (a) to (d) used in the present invention, which are completely different from the hydrophilic surfactants of 10 or more HLB, or any compounds

analogous thereto. Accordingly, it is respectfully submitted that it would not have been obvious to one of ordinary skill in the art to substitute the stabilizer of Unger for that in the composition of JP '562.

Moreover, even if JP '562 and Unger were somehow combined, one of ordinary skill in the art would not expect the superior results provided by the present invention as a result of selecting a specific compound from the wide range of stabilizers disclosed by Unger and substituting the surfactant disclosed in JP '562 with the compound.

For the foregoing reasons, it is respectfully submitted that claims 5, 7-9, 11, 12, 21, 23-25, 27, 28 and 33 are patentable over the cited art, and withdrawal of the rejection is respectfully requested.

III. Response to Rejection of Claim 17 under 35 U.S.C. § 103(a)

Claim 17 remains rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over JP '562 and further in view of Yugari (US 2001/0047162).

Applicants respectfully traverse the rejection for the reasons of record and for the following reasons.

Claim 17 relates to a container for containing the fat emulsion of claim 1. However, an important feature of invention covered by claim 17 is the fat emulsion used, in addition to the configuration of the container. That is, one of the multi-compartments of the container contains the fat emulsion of claim 1. As described above, the fat emulsion of claim 1 is patentable over JP '562, and thus, claim 17, which relates to the container for containing such a fat emulsion is not obvious in view of the combination of JP '562 and Yugari.

Accordingly, withdrawal of the rejection is respectfully requested.

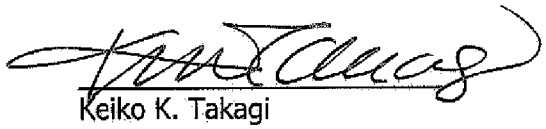
IV. Conclusion

In view of the foregoing, reconsideration and allowance of claims 1-5, 9, 11-13, 15-21, 23-25, 27-29 and 31-33 is respectfully requested.

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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